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CLEVELAND, OH 44114				
EXAMINER				
TANNER, JOCELYN C				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/549,355

Applicant(s)

CARO ET AL.

Examiner

JOCELIN C. TANNER

Art Unit

3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 September 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-6,9,10 and 12-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-6,9,10 and 12-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 September 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

This Office Action is in response to the Amendment filed 30 September 2008.

Claims 1, 3-6, 9, 10, 12-23 are now pending. The Examiner acknowledges the amendments to claims 3-6 and the cancellation of claims 2, 7, 8, and 11.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. **Claims 12-19, 21 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Houston et al. (US PGPub No. 2002/0179166A1).**

3. Regarding claim 12, Houston et al. discloses a stent (300) having an expanded configuration with a helical center line and a helix angle of 8° that is within the claimed range of less than or equal to 65° ([0010], [0021], [0050], [0051], Fig. 4A). Houston fails to disclose an amplitude having a value less than or equal to 0.7 of the internal diameter of the tubing.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided tubing having a helical center line with a claimed value of an amplitude less than or equal to 0.7 of the internal diameter, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

4. Regarding claim **13**, Houston et al. discloses a helical centre line formed by internal ridging that has an amplitude and tubing with an internal diameter. Houston fails to disclose the value of 0.05 calculated by dividing the amplitude of the helical centre line by the internal diameter of the tubing.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided tubing with the claimed values found by dividing the amplitude of the helical centre line by the internal diameter, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

5. Regarding claim **14**, Houston et al. discloses a stent that is substantially free of ribs that would interfere within the flow lumen in its expanded condition (Fig. 4A).

6. Regarding claim **15**, Houston et al. discloses Houston et al. discloses a stent (300) having an expanded configuration with a helical center line and a helix angle of 8° that is within the claimed range of less than or equal to 15° ([0010]).

7. Regarding claim **16**, Houston et al. discloses a stent having a circular cross-section (Fig. 4A).

8. Regarding claim **17**, Houston et al. discloses a helical center line of the stent extending over part of the overall length of the stent (Fig. 4A).
9. Regarding claim **18**, Houston et al. discloses a helical center line of the stent extending over substantially the entire length of the stent (Fig. 4A).
10. Regarding claim **19**, Houston et al. discloses a helical center line following a substantially helical path about a curved axis (Fig. 4A).
11. Regarding claim **21**, Houston et al. discloses a helical centre line formed by internal ridging that has an amplitude and tubing with an internal diameter. Houston fails to disclose the value of 0.1 calculated by dividing the amplitude of the helical centre line by the internal diameter of the tubing.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided tubing with the claimed values found by dividing the amplitude of the helical centre line by the internal diameter, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.
12. Regarding claim **23**, Houston et al. discloses a stent having a helical portion that has the same number of turns in the expanded and collapsed conditions (Fig. 6).

13. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Houston et al. (US PGPub No. 2002/0179166A1) in view of Igaki et al. (US Patent No. 5,733,327).

Regarding claim 20, Houston et al. discloses all of the limitations previously discussed except for a pharmaceutical coating.

Igaki et al teach coating a stent to provide locally limited and long-term dosage of drugs (column 2, line 51 and column 3, lines 19-22).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the stent of Houston et al., with the coating or drug induced fiber, as taught by Igaki et al., to provide locally limited and long-term dosage of drugs.

14. Claims 1, 3-6 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Houston et al. (US PGPub No. 2002/0179166A1) in view of Hogan (US Patent No. 6,569,191).

15. Regarding claim 1, Houston et al. discloses a stent (300) having a helix structure and formed of a synthetic material and having an outer wall that radially expands. Houston fails to disclose wall portions that have more of a resistance to extension than the helical portions.

Hogan teaches an expandable stent wherein rigid longitudinal strips (40) are attached to the helically wound threads that form the wall of the stent and exert an increased longitudinally constricting force (column 7, lines 1-12, Fig. 4).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided longitudinal extension resistance to the stent of Houston et al., as taught by Hogan, to increase radial expansion to obtain a desired final diameter.

16. Regarding claim 3, Hogan teaches helical supplemental threads (30) of different material or thickness that increase the amount of stent forming material (column 6, lines 33-37, Fig. 2).

17. Regarding claim 4, Houston et al. discloses a stent having curved or "bent" portions wherein the bent portions remain bent when expanded (Figs. 4A and 6).

18. Regarding claims 5 and 6, Hogan teaches a self-expanding and balloon-expandable stent (column 8, lines 17-21).

19. Regarding claim 22, Houston et al. discloses a stent (300) undergoing a turn of the helix wherein the stent has a helical configuration with at least one helical turn (Fig. 4A).

20. Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Houston et al. (US PGPub No. 2002/0179166A1) in view of Hogan (US Patent No. 6,569,191), further in view of Inderbitzen et al. (US Patent No. 5,484,411).

21. Regarding claim 9, Houston et al. discloses all of the limitations previously discussed except for a balloon expandable stent having a balloon with a helical portion of an expandable wall that extends longitudinally and circumferentially and resists extension more than portions of the wall that are adjacent to the helical portion.

Hogan teaches a balloon expandable stent that radially expands the stent (column 8, lines 17-34).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the stent of Houston with a balloon for expansion means, as taught by Hogan, since it was well known in the art to expand a stent using balloon expansion.

The combination of Houston et al. and Hogan fails to disclose a balloon having an expandable wall that resists extension more helical portions of the balloon.

Inderbitzen et al. teaches expandable balloon used in angioplasty procedures including a longitudinally extending spiral wall (38) extending from the distal to proximal end of the balloon, formed integrally with the exterior surface of the balloon and radially restricting the expansion of the balloon along the longitudinally extending spiral path (column 3, lines 45-53, Fig. 2).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have constructed the balloon of the combination of

Houston et al. and Hogan, with a helical portion, as taught by Inderbitzen et al., to exhibit a low crossing profile and to avoid the need to rotate the balloon within a vessel to ensure dilation.

22. Regarding claim 10, Inderbitzen et al. teaches a balloon having an exterior surface or expandable wall wherein the wall thickness is greater in sections include a spiral wall or "helical portion" (38) (Fig. 2).

Response to Arguments

23. Applicant's arguments with respect to claims 1, 3-6, 9, 10, 12-23 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

24. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOCELIN C. TANNER whose telephone number is (571)270-5202. The examiner can normally be reached on Monday through Thursday between 9am and 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jocelin C. Tanner/
10/29/2008
Examiner, Art Unit 3731

/Todd E Manahan/

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Supervisory Patent Examiner, Art Unit 3731